

AMENDMENTS TO THE DRAWINGS

The attached sheet(s) of drawings includes changes to Fig. 28. The descriptive text has been removed from the figure. No new matter has been added.

Attachment: Replacement sheet

REMARKS

Reconsideration of the Application, as amended, is respectfully requested.

I. Status of the Claims

Claims 6, 7, and 9 are withdrawn. Claim 7 has been amended to be in conformance with the disclosure of Fig. 27 and the amended specification.

Claims 1-5, have been amended, the amendments do not add new matter.

Claims 1-5, 8, and 10-22 are presented for Examination.

Claims 1-5, 8, and 12-22 have been amended to overcome the objections noted by the Examiner. The amendment to claim 8 results in that claims 10 and 11 did not need to be amended to be in accordance with U.S.P.T.O practice. Applicants request the objections be withdrawn.

II. Status of the Specification and Drawings

The Specification has been amended to correct informalities. A mark up copy and a clean copy of the substitute specification are provided. No new matter has been added.

For example, the term "outer vessel" was changed to "package" to achieve consistency in usage. Furthermore, the phrase "individual wrapping container" was changed to "individual wrapping body" to be consistent with the usage of the phrase in the specification and to distinguish from the term "container" used in reference with the package. For example, previously, reference 42 referred to an individual wrapping body and reference 44 referred to an individual wrapping container (see, Clean Specification, page 26, line 22 to page 27, line 7). However, both are individual wrapping bodies as described in pages 26 and 27, noted above. Therefore, by this amendment, usage of the term "wrapping body" is also made consistent within the specification.

Further, the mark up copy of the Specification has been marked to show the amendments made in the Second Preliminary Amendment filed November 11, 2003.

The Drawings have been corrected. Figure 28 was amended to remove the descriptive text and, for Figure 27, the description in the specification has been corrected to conform to the figures. No new matter has been added.

The Abstract has been amended to conform to U.S.P.T.O practices and is attached as a separate page at the back of the clean copy of the specification.

No new matter has been added and Applicants respectfully request that the objections to the Specification, Abstract and Drawings be withdrawn.

III. Election/Restrictions

With regard to the election of species described in the Office Action, Applicants respectfully asserted that claims 6 and 7 read on the elected species, Fig. 27B. The description regarding Fig. 27 has been corrected in the specification to conform to what is shown in Fig. 27. Moreover, claim 7 has been amended to be consistent with the now proposed substitute specification. Therefore, Applicants respectfully request that claims 6 and 7 be reinstituted for consideration.

IV. Rejections under 35 USC § 112, Second Paragraph

Claims 1-5, 8 and 10-22 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 8 and 10-22 have been amended to obviate the indefinite rejection and provide proper antecedent basis.

V. Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-5, 8, and 10-22 have been rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully submit that the specification, including the claims, as amended, enable one skilled in the art to make the claimed invention. Accordingly, Applicants request that the rejection be withdrawn.

VI. Rejections under 35 U.S.C §§ 102/103

Claims 1-4, 12-13, 18-19, and 22 have been rejected under 35 USC §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over McFall et. al., PCT '689.

Amended independent claim 1 includes the features of over-wrapping film and the opening for introducing the sterilization gas into the container. McFall does not disclose the process by the sterilization gas and the structure of the over-wrapping film. Therefore, the present invention is novel over McFall. Further, McFall does not include any suggestion to modify McFall's invention to have the specific structure of the container, for example, the opening for the sterilization gas and the over-wrapping film, and therefore the present invention is not obvious over McFall. In addition, claim 1 includes the element of the direct method of the sterilization test, which is supported in the disclosure on page 48 of the Specification.

Claims 5 and 14-15 have been rejected under 35 U.S.C. § 103(a) as obvious over PCT '689 in view of Wierlacher PCT '096. Applicants respectfully submit that claims 5 and 14-15 depend either directly or indirectly from independent claim 1 and are allowable for at least the same reasons set forth above.

Claims 8, 10-11, 16-17 and 20-21 have been rejected under 35 U.S.C. § 103(a) as obvious over McFall in view of Brisebois et al. Applicants respectfully traverse the Examiner's rejection.

Applicants respectfully submit that neither McFall nor Brisebois, either alone or in combination, teach or suggest Applicants claimed invention. In particular, neither reference teaches or discloses a container adapted to include an individual wrapping body including over-wrapping film and an opening for introducing sterilization gas into the container of the over-wrapping body. As noted, McFall does not disclose the process by the sterilization gas and the structure of the over-wrapping film. Further, neither McFall nor Brisebois include any suggestion to modify McFall's invention to have the specific structure of the container, for example, the opening for the sterilization gas and the over-wrapping film. Accordingly, Applicants respectfully request that the rejection be withdrawn.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Dated: August 23, 2006

Respectfully submitted,

By 

Louis J. Del Giudice

Registration No.: 47,522

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant